510(k) Summary
SAM Medical Products, Inc.
SAM® Junctional Tourniquet

MAR 7 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K123694

Contact Details

Applicant Name: SAM Medical Products, Inc

SAM Medical Products, Inc

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Wilsonville, OR 97070

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QARA Manager

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Date Prepared: November 15, 2012

Device Name

Trade Name: SAM® Junctional Tourniquet

Common Name: Vascular Clamp

Classification Name: Clamp Vascular

Legally Marketed Predicate Device(s)

510(k) Number	Product Code	Trade Name	Applicant
K102025	DXC	Combat Ready Clamp	Combat Medical Systems LLC 6441-D Yadkin Rd Fayettville, NC 28303
Exempt	IPW	SAM Pelvic Sling	SAM Medical Products 27350 SW 95th Ave. Suite 3038 Wilsonville, OR 97007

Device Description

The SAM Junctional Tourniquet addresses the issue of non-tourniquetable inguinal hemorrhage. The device is designed to control bleeding in the inguinal area where standard Tourniquets cannot be used. The SAM Junctional Tourniquet is used to control bleeding for up to 4 hours.

A key feature of the device is a belt/buckle system which provides feedback to the user after a minimum circumferential force around the patient is obtained, after which an inflatable point pressure device (PPD) is manually activated to occlude an artery or to provide compressive force over a Hemostatic agent.

The SAM Junctional Tourniquet can also be used as a Circumferential Pelvic belt for pelvic fracture immobilization.

Intended Use/Indications for use

The SAM Junctional Tourniquet is indicated for battlefield and trauma situations:

- To control difficult bleeds in the inguinal area.
- To immobilize a pelvic fracture

Substantial Equivalence Comparison

The SAM® Junctional Tourniquet has new technological characteristics. These new characteristics do not introduce new concerns of safety or performance.

The SAM Junctional Tourniquet (SJT) is similar in design and intended use to marketed products manufactured by:

1) Combat Ready Clamp (CRoC), Combat Medical Systems

	Attribute	SJT	CRoC
1	Inguinal Trauma Patients	Yes	Yes
2	Indicated for use to control difficult bleeds in the inguinal area	Yes	Yes
3	Indicated for immobilization of pelvic fractures	Yes	No
4	Product code	DXC	DXC
5	Circumferential belt	Yes	Yes
6	Point pressure	Yes	Yes
7	Point pressure mechanism	Manual, Pneumatic	Manual, Screw
8	Force control mechanism	Spring Controlled Buckle	None
9	Materials	Metal, Injection Molded Plastic, Textile	Metal, Injection Molded Plastic, Textile
10	Biocompatibility	Yes, per ISO 10993-1 requirements	Not listed in 510k summary
11	Shelf Life	N/A	N/A
12	Sterile Product	No	No
13	Testing to Predicate	Cadaver, Bench	Cadaver, Bench

Non-clinical Testing

Bench Testing:

- PPD Burst Pressure Test
- PPD Four Hour Stability Test
- The raw materials meet USP Plastic Class VI and ISO 10993-1 requirements
- Human Simulation Testing
- Cadaver

Clinical Testing

No clinical testing was performed.

Conclusion

The SAM Junctional Tourniquet is substantially equivalent to the Combat Ready Clamp. The SAM Junctional Tourniquet introduces new design, materials and technology, but these differences do not introduce new safety or performance concerns. The evidence from the performance bench testing further supports the substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 7, 2013

SAM Medical Products
C/O Jack N. McCutcheon
27350 SW 95th Ave Ste 3038 Bldg 30
Wilsonville, Oregon 97070

Re: K123694
Trade/Device Name: SAM Junctional Tourniquet
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: January 23, 2013
Received: January 24, 2013

Dear Mr. McCutcheon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number: K123694

Device Name: SAM® Junctional Tourniquet

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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